

REMARKS

The invention relates to apparatus for performing liquid chromatography, which involves flow of a liquid carrying a sample, called the mobile phase, through a porous media, called a stationary phase. Different compounds in the sample will have differing rates of migration through the media, which causes the separation of the components in the subject sample. Liquid chromatography is commonly performed with reusable columns or with disposable cartridges, both of which are usually cylindrical, in which the media bed, typically resin beads, is bounded axially by porous plates, or plates containing defined flow paths, through which the mobile phase will flow into and from the media bed. Voids in the bed of stationary phase resin beads that may have resulted during shipping and other nonuniform packing conditions can deleteriously affect the operation of chromatography column and the accuracy of results.

More recently, a different type of stationary phase, called a "monolith," has been introduced. In this type of stationary phase, the polymer separation media is provided as a porous unitary structure, which can be formed inside a column by polymerizing the material inside a column, or can be preformed and then inserted into a column. Because the stationary phase is provided as unitary structure, it will not suffer from the shifting of individual particles as can happen with the resin beads.

The invention, as claimed in independent claim 1, relates to a disposable chromatography cartridge that contains a monolith chromatography stationary phase inside a vessel that has a flexible wall that is deformable by externally applied force so as to reduce the volume within the vessel. The application of external force and deformation of the flexible wall advantageously and unexpectedly provide for improved separation of the chemical compound passing through the monolith chromatography stationary phase. It is believed that the external force tends to close channels that may otherwise exist between the outside of the stationary phase and the inside of the wall and which otherwise may present low pressure by-pass channels. The external force may also tend to provide for more uniform flow through the stationary phase by closing voids therein. This improved performance is unexpected for the monolith stationary phase, because the monolith stationary phase does not have the problem of shifting of resin beads that is

known to occur with typical media, such that improved uniformity is expected for use of a deformable wall cartridge with the resin beads but not for the monoliths.

Claim 1 stands rejected as anticipated by or obvious over Frechet U.S. Patent No. 5,334,310. Hatch U.S. Patent No. 6,238,565 is also cited for disclosure a monolith that is polymerized in situ in a tube or formed outside a tube and then inserted in the tube.

These references do not disclose or suggest in any way the use of a vessel with a flexible walls or the resulting unexpected results of improved performance for a monolith device, and claim 1 is patentable under 35 USC 102(b) and 103(a) over these references.

Claim 1 is also rejected as obvious over each of Leavesley U.S. Patent No. 5,601,708, McDonald U.S. Patent No. 4,250,035 and Conroy WO 97/43024 in view of Frechet or Hatch.

The first three references are said to disclose a vessel with a flexible wall, and the last two are cited for disclosure of monoliths. The first three references nowhere disclose or suggest the use of monoliths, and the last two nowhere disclose the use of a vessel with a flexible wall. There is no motivation to combine the teachings of these references. In particular, because the monolith beds do not suffer from the known problem of shifting that occurs in beds with resin beads, it would not be expected that the monolith beds would obtain improved uniformity with a deformable wall cartridge the way that the resin beads do.

The references, taken alone or in combination, nowhere suggest the combination claimed in claim 1, and claim 1 is patentable under 35 USC 103(a) over these references.

The remaining claims depend on claim 1 and are allowable with it.